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May 10, 2022

Robert M. Califf, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Commissioner Califf,

On behalf of over 220 children's hospitals across the country, we are reaching out to ask that you prioritize pediatric needs by addressing two critical shortage issues that are impacting children's hospitals and the children and families they serve. Both powdered infant formula and valves used for infant and child feedings through IV Total Parenteral Nutrition (TPN) are facing acute shortages, with few viable solutions currently being brought forth to mitigate the hardship felt by families and patients. We urge swift action by the FDA to stabilize the market and identify safe and appropriate solutions to address these critical shortages affecting children.

First, it is critical that the agency quickly makes available information about alternative and safe formula options while simultaneously prioritizing the safety of the manufacturing process. We ask that you disseminate a comprehensive list of powdered infant formula substitutions to help families impacted by the current shortage stemming from the recall that began on Feb. 17. The shortage has drastically limited options for infants and children across the country and is particularly problematic for our sickest patients who are on specialized formulas, such as elemental, metabolic and renal formularies. With an estimated 30% of formula brands in the U.S. out-of-stock, some families report making at-home substitutes, which is dangerous for the sickest children with specialized formula needs. Many of these patients must go to the hospital as a last resort to receive feedings through IV TPN, placing a significant burden on families that must make unnecessary trips to the hospital. The fallout from this formula shortage is likely to have far-reaching negative consequences if the manufacturing issues are not addressed and if families remain in the dark about appropriate substitutes for their children's specialized formula.

Second, we ask that you immediately address the Baxter ExactaMix valve shortage by prioritizing children's hospitals' ExactaMix valve allocation for their TPN systems, understanding that they have no alternatives for NICU care. As you may know, ExactaMix valves connect to the TPN compounder and mix the formula solution. Currently, these valves are in short supply and, as a result, all entities that receive these valves have been placed on a 65% allocation plan. The manufacturer has put forth mitigation strategies to help entities deal with the reduced supply, but many of those strategies, while well-intentioned, do not work for the premature infants that children's hospitals treat. For example, neonates have weight-based caloric requirements that are higher than they will be at any point in life, have a larger need for electrolytes and need specific pH to optimize protein and necessary electrolytes. Because of these specific clinical needs, neonates are not candidates for commercial parenteral nutrition systems, or "pre-mixed" TPN, offered as a mitigation strategy. Due to the high volume of premature patients in our children's hospitals who are impacted by this shortage and the inability to use substitutes at such a critical life stage, we ask the FDA to require the manufacturer to provide a full allocation to children's hospitals, even amidst the shortage.

*Champions for Children's Health*

Please let us know how we can work with you to best support the vulnerable pediatric patients negatively impacted by these ongoing shortages.

Best regards,

A handwritten signature in black ink, appearing to read "Mark Wietecha". The signature is fluid and cursive, with the first name "Mark" being more prominent than the last name "Wietecha".

Mark Wietecha  
Chief Executive Officer  
Children's Hospital Association